



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dr. Lynne Hamilton
Regulatory Affairs
Radox Laboratories Ltd.
Ardmore, Diamond Road,
Crumlin, Co. Antrim
United Kingdom
BT29 4QY

NOV 26 2002

Re: k021897
Trade/Device Name: HAEMOGLOBIN A_{1c}
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP
Dated: November 15, 2002
Received: November 19, 2002

Dear Dr. Hamilton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

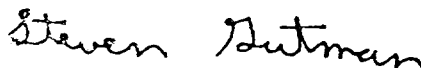
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) Not Known
Device Name HAEMOGLOBIN A_{1c}

Indications For Use :

The Randox Laboratories Limited Haemoglobin A_{1c} Test Kit is an *in vitro* diagnostic reagent for the quantitative determination of haemoglobin A_{1c} (HbA_{1c}) in whole blood. The method is an immunological assay. Both the concentration of HbA_{1c} and the concentration of total haemoglobin are measured. The reported HbA_{1c} result is calculated as a percentage of the total haemoglobin concentration.

Measurements of percentage HbA_{1c} are effective in monitoring long-term glucose control in individuals with diabetes mellitus.

This application sheet has been developed for the Hitachi 717 clinical chemistry analyser and must be used by suitably qualified laboratory personnel under appropriate clinical laboratory conditions.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional format 1-2-96)

J. P. Reeves for J. Bantista
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number 1C021897